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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,186	09/28/2001	Jeffrey T. Ellis	50623.55	5975

7590 05/30/2003  
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding. 5

## Office Action Summary

Application No.

09/967,186

Applicant(s)

ELLIS ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3, 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statements filed 1/16/03, 6/27/02 and 8/5/02 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information disclosure statements have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 6, 7, 8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/02845 to Wink et al. in view of U.S. Patent No. 6,336,906 to Hammarström et al.

In reference to claims 1, 6, 7, 8, 14 and 15, Wink et al. discloses a sensor with an electrically conductive substrate having an amperometric response that is unaffected by the presence of nitric oxide; and a coating for reacting with nitric oxide or superoxide so as to cause a change in the electrochemical potential of the nitric oxide (Page 7, line 31 – Page 8, line 2). The sensor comprises a catalytic material capable of oxidizing nitric oxide (Page 11, lines 6 – 24). Wink et al. discloses the sensor for detecting and/or measuring NO (nitric oxide) in vivo (Page 12, lines 5 – 9). However, Wink et al. fails to disclose the sensor being included in an elongated wire assembly for percutaneously or subcutaneously penetrating into a vessel. However, Hammarström et al. teaches an elongated wire assembly wherein a sensor is included in the assembly for percutaneously or

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subcutaneously penetrating into a vessel (Col. 2, lines 18 – 28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to mount the sensor as disclosed by Wink et al. in an elongated wire assembly as taught by Hammarström et al. in order decrease the stress exerted on the sensor during sharp vessel turns (Col. 4, lines 20 – 23) when performing an in vivo measurement of NO.

3. Claims 1 – 5, 7 – 9, 11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,582,170 to Soller in view of U.S. Patent No. 6,336,906 to Hammarström et al.

In reference to claims 1 – 5, 7 – 9, 11, 13 and 15, Soller discloses an elongated assembly and a method using the elongated assembly comprising: positioning the elongated assembly into a designated region within a blood vessel (Col. 11, lines 16 – 19); measuring the level of nitric oxide (NO) in the region of the vessel (Col. 11, line 20); delivering a stimulant to increase the production of NO (Col. 11, lines 21 – 36); wherein the elongated assembly comprises a sensor having: a compound which can react with NO causing the optical properties of the compound to change; and an optical system for measuring the optical properties of the compound. Soller discloses the optical system including a first optic line for illuminating a light on the compound and a second fiber optic line to receive the light from the compound and to relay the received light to a detector (Col. 8, line 36 – 56). Soller discloses the sensor comprising a catalytic material capable of oxidizing NO (Col. 10, lines 23 – 44). However, Soller fails to disclose the elongated assembly being an elongated wire assembly configured to allow a catheter assembly to be disposed over a portion thereof, and having a distal section being more flexible than the proximal section. However, Hammarström et al. teaches an elongated wire assembly wherein a sensor is included in the assembly for percutaneously or subcutaneously penetrating into a vessel (Col. 2, lines 18 – 28). The elongated wire assembly as

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disclosed by Hammarström et al. has a distal section more flexible than the proximal section and is inherently configured to allow a catheter assembly to be slidably disposed over a portion thereof. It would have been obvious to one having ordinary skill in the art at the time the invention was made to mount the sensor as disclosed by Wink et al. within the elongated wire assembly as taught by Hammarström et al. in order to decrease the stress exerted on the sensor during sharp vessel turns (Col. 4, lines 20 – 23).

4. Claims 10, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,582,170 to Soller in view of U.S. Patent No. 6,336,906 to Hammarström et al. as applied to claim 8 above, and further in view of U.S. Patent No. 5,945,542 to Cooke et al.

In reference to claims 10, 12 and 16, the method as disclosed by Soller in view of Hammarström et al. as discussed above fails to disclose the steps of inserting a catheter over the wire assembly, delivering the stimulant acetylcholine, and the designated region within the vessel being affected by restenosis. Cooke et al. discloses a method wherein an infusion catheter is advanced over a guide wire to infuse acetylcholine (Col. 18, lines 35 – 38). Cooke et al. teaches that administering acetylcholine diminishes the formation of atherosclerotic plaque and restenosis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Soller in view of Hammarström et al. to include the steps of advancing a catheter over the guidewire to administer the stimulant acetylcholine to an area of restenosis in a vessel as taught by Cooke et al. in order to diminish the formation of atherosclerotic plaque and restenosis by inhibiting adhesion of monocytes and platelets, and by reducing the proliferation of vascular smooth muscle cells (Col. 18, line 63 – Col. 19, line 3).

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*Conclusion*

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Publication 2002/0072680


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF  
May 27, 2003



MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700